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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/493,545 01/28/00 ZHANG

R GI 5340A

025291 HM22/0430
AMERICAN HOME PRODUCTS CORPORATION
PATENT SECTION
FIVE GIRALDA FARMS
MADISON NJ 07940-0874

EXAMINER

ROBINSON, P.	
ART UNIT	PAPER NUMBER

1653
DATE MAILED:

04/30/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/493,545

Applicant(s)

ZHANG ET AL

Examiner

Patricia A. Robinson

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 February 2001.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 18) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

The amendment filed in Paper No. 7 on 2/12/01 was received, entered and considered.

The claims currently pending are 1-14 and newly added claims 15-21, all of which were examined herein.

Response to Arguments

Applicant's arguments filed 2/12/2001 have been fully considered but they are not persuasive.

The rejection of claims 1,2,5,7-9, 12 and 14 made under 35 U.S.C. 112, 2nd is **withdrawn**.

Applicant's argue that Hattersley teaches BMP-2 with PTH for the regeneration of articular cartilage while the instant application claims just BMP. The claims contain the word "comprising" which is an open term and thus any art that is identified can have BMP plus any other components and still read on the claim if it being used for the cartilage repair.

Lastly Applicant's agrue that claims 2 and 9 require BMP in combination with a suitable tissue source, which as defined on page 2, lines 23-29 of the Specification include chondrocytes and osteochondral grafts.

Hattersley et al. teaches that PTHrP is essential in chondrocyte development and maturation and is used in combination with BMP. (See, Col. 2, lines 1-3; Col. 4, lines 10-12 and Col. 5, lines 10-26).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hattersley et al. taken with Nevo et al.

The Hattersley et al. reference teaches compositions comprising BMP-2 and other growth and differentiation factors (transforming factor beta superfamily members) useful in methods of repairing articular cartilage, as well as in inducing cartilage formation. (See col. 1, lines 9-24; col. 2, lines 30-63; col. 3, lines 2-31; and col. 4, line 50- col. 5, line 4). Hattersley et al. also teaches that protein compositions comprising BMP-2 and BMP-13 are useful in methods of inducing the formation of other types of tissues, such as tendons and ligaments. (See col. 5, lines 25-47). Lastly, Hattersley et al. teaches that PTHrP is essential in chondrocyte development and maturation and is used in combination with BMP. (See, Col. 2, lines 1-3; Col. 4, lines 10-12 and Col. 5, lines 10-26). Nevo et al. teaches compositions for repairing damaged cartilage which include chondrocytes and other growth factors. (See Col. 1, lines 13-15, 22-24 and 33-

34). Nevo et al. also teaches osteochondral grafting in repairing damaged cartilage. Thus, where Hattersley et al. teaches chondrocytes as a tissue source in cartilage development, it would have been obvious to one of ordinary skill in the art to have modified Hattersley et al. by using the early teachings of Nevo et al. to further support chondrocytes as a tissue source, as well as osteochondronal grafts. Therefore, the claimed invention was within the ordinary skill in the art to make and use at the time it was made and was as a whole, *prima facie* obvious.

Conclusion

No claim is allowed.

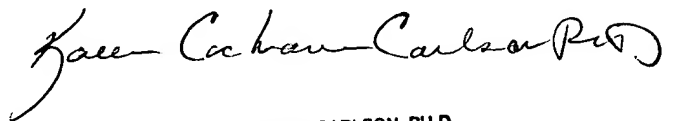
Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Robinson whose telephone number is 703-305-0096. The examiner can normally be reached on 8:00 - 4:30 Monday - Friday, off alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 703-308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

A handwritten signature in cursive script, reading "Karen Cochrane Carlson".

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER

PAR
April 17, 2001